I. The Office Action

The August 25, 2003 office action in this application (hereafter the "Office Action"):

1. rejected claims 1, 5, 6 and 9-12 under 35 U.S.C. §101 as claiming the same invention as that of claims 1-3 and 6-9 of U.S. patent 6,358,513.

2. rejected claims 1-13 under the judicially created doctrine of obviousness type double patenting over claims 1-7 of U.S. patent no 6,585,970.

3. rejected claims 1-13 under the judicially created doctrine of obviousness type double patenting over claims 1, 2, 4-8, 16 and 17 of U.S. patent no 6,524,580.

4. provisionally rejected claims 1-13 and 22-23 under the judicially created doctrine of obviousness type double patenting over claims 1-11 of copending application serial number 10/099,238.

5. rejected claim 8 under 35 U.S.C. second paragraph.

Applicant responds to the Office Action as follows.

II. Rejection of Claims 1, 5, 6 and 9-12 under 35 U.S.C. §101

The Office Action rejected claims 1, 5, 6 and 9-12 under 35 U.S.C. §101 as claiming the same invention as that of claims 1-3 and 6-9 of U.S. patent 6,358,513.

The claims have been amended to add the limitations of claim 2 to the rejected claims. Claim 2 was not rejected. Hence, adding the limitations of claim 2 to all the claims overcomes the rejection and the rejection should therefore be withdrawn.

Applicants hereby cancel claim 2 without prejudice to further prosecution as a later date

III. Rejection of Claims 1-13 for Obviousness Type Double Patenting over Claims 1-7 of U.S. Patent 6,585,970

The Office Action rejected claims 1-13 under the judicially created doctrine of obviousness type double patenting over claims 1-7 of U.S. patent 6,585,970. An executed terminal disclaimer in enclosed. Hence, the rejection should be withdrawn.

IV. Rejection of Claims 1-13 for Obviousness Type Double Patenting over Claims 1-2, 4-8 and 16-17 of U.S. Patent 6,524,580

The Office Action rejected claims 1-13 under the judicially created doctrine of obviousness type double patenting over claims 1-2, 4-8 and 16-17 of U.S. patent 6,524,580. An executed terminal disclaimer in enclosed. Hence, the rejection should be withdrawn.

IV. Provisional Rejection of Claims 1-13 for Obviousness Type Double Patenting over claims 1-11 of Copending Application Serial Number 10/099,238

The Office Action provisionally rejected claims 1-13 under the judicially created doctrine of obviousness type double patenting over claims 1-11 of copending application serial number 10/099,238. An executed terminal disclaimer in enclosed. Hence, the rejection should be withdrawn.

VI. Rejection of Claim 8

The Office Action rejected claim 8 because of use of the word "about" in the phrase "about 1 unit". This phrase in claim 1 has been amended to "1 unit". Hence, the rejection should be withdrawn.

VII. New Claim 14

New Claim 14 is supported by at least the nine Examples in the application, all of which indicate efficacy of the claimed method for up to six months.

VIII. Conclusion

All issues raised by the Office Action have been addressed. Allowance of claims 1 and 3-14 is requested.

Respectfully submitted,

Date: January 5, 2004

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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10

I hereby certify that this Response to Office Action and 3 Terminal Disclaimers and any other documents referred to as enclosed therein are being deposited with the United States Postal Service on this date **January 5, 2004** in an envelope as "Express Mail Post Office to Addressee" Mailing Label number **EV193720760US** addressed to, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Susan Bartholomew
Name of person mailing paper

Date: January 5, 2004

Signature of person signing paper

AMENDED CLAIMS

1. (currently amended) A method for treating Hashimoto's thyroiditis, the method comprising the step of local administration of a therapeutically effective amount of a botulinum toxin to the thyroid gland of a patient, wherein the botulinum toxin is administered in an amount between 1 unit and 20,000 units, thereby ameliorating severity of Hashimoto's thyroiditis for between two months and six months.

2. (cancelled)

3. The method of claim 1, wherein the botulinum toxin is locally administered in an amount of between about 10^{-3} U/kg and about 35 U/kg.

4. The method of claim 1, wherein the botulinum toxin is made by a Clostridial bacterium.

5. The method of claim 1, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

6. The method of claim 1, wherein the botulinum toxin is botulinum toxin type A.

7. The method of claim 2, wherein the botulinum toxin is administered to the thyroid gland of the patient by placement of a botulinum toxin implant on or in the thyroid gland.

8. The method of claim 1, wherein the botulinum toxin is botulinum toxin type A and the botulinum toxin administered to the thyroid gland of the patient in an amount ~~of~~ between ~~about~~ 1 unit and about 100 units.

9. A method for treating Hashimoto's thyroiditis, the method comprising the step of local administration of a therapeutically effective amount of a botulinum toxin to a thyroid gland of a patient by direct injection of the botulinum toxin into the thyroid gland, wherein the botulinum toxin is administered in an amount between 1 unit and 20,000 units, thereby ameliorating severity of Hashimoto's thyroiditis for between two months and six months.

10. The method of claim 9, wherein the botulinum toxin is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

11. The method of claim 9, wherein the botulinum toxin is botulinum toxin type A.

12. The method of claim 9, wherein the botulinum toxin is botulinum toxin type B.

13. A method for amelioration of Hashimoto's thyroiditis, the method comprising the step of local administration of between 1 unit and 200 units of a botulinum toxin type A to a patient, thereby easing the severity of Hashimoto's thyroiditis for between two months and six months.

14. (new) A method for treating Hashimoto's thyroiditis, the method comprising the step of local administration of a therapeutically effective amount of a botulinum toxin to the thyroid gland of a patient, wherein the botulinum toxin is administered in an amount between 1 unit and 20,000 units, thereby treating Hashimoto's thyroiditis for up to six months.